***Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Animal Food* – Tracked changes showing the regulatory text of the proposed rule with this title that issued on October 29, 2013, in the *Federal Register* as revised by the supplemental notice of proposed rulemaking with the same title that went on display in the *Federal Register* on September 19, 2014, with an anticipated publication date of September 29, 2914.**

In the Federal Register of October 29, 2013 (78 FR 64736), the Food and Drug Administration (FDA or we) issued a proposed rule (the 2013 proposed rule for preventive controls) for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals. This proposed rule would establish requirements for Current Good Manufacturing Practice (CGMP) and hazard analysis and risk-based preventive controls for animal food.

On September 19, 2014, we announced an expected date for publication in the Federal Register (i.e., September 29, 2014) for a supplemental notice of proposed rulemaking (the 2014 preventive controls supplemental notice) to amend certain specific provisions of the 2013 proposed preventive controls rule and provide regulatory language for public comment on certain potential requirements. For the convenience of readers and ease of reference, the document below largely identifies the proposed additions and deletions in the 2014 preventive controls supplemental notice relative to the 2013 proposed preventive controls rule, including regulatory text for the potential requirements described in the 2014 preventive controls supplemental notice. In general, we tried to identify the proposed additions and deletions in a way that we believe would be most useful to readers. For example, where text was moved in the codified, we did not show it as new text.

List of Subjects

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 117

Food packaging, Foods.

21 CFR Part 225

Animal drugs, Animal feeds, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

21 CFR Part 500

Animal drugs, Animal feeds, Cancer, Labeling, Packaging and containers, Polychlorinated biphenyls (PCB's).

21 CFR Part 507

Animal foods, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

21 CFR Part 579

Animal feeds, Animal foods, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR chapter I be amended as follows:

PART 16--REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

1. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: 15 U.S.C. 1451-1461; 21 U.S.C. 141-149, 321-394, 467f, 679, 821, 1034; 28

U.S.C. 2112; 42 U.S.C. 201-262, 263b, 364.

2. In § 16.1, in paragraph (b)(2) add the following entry in numerical order to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(2) * * *

§§ 507.60 through 507.~~83~~ 85 (part 507, subpart D) relating to withdrawal of exemption applicable to a qualified facility.

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PART 117--CURRENT GOOD MANUFACTURING PRACTICE AND HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD

3. The authority citation for 21 CFR part 117, as proposed to be added on January 16, 2013 (78 FR 3646), continues to read as follows:

Authority: 21 U.S.C. 331, 342, 343, 350d note, 350g, 350g note, 371, 374; 42 U.S.C. 243, 264, 271.

4. In part 117, as proposed to be added on January 16, 2013 (78 FR 3646), add § 117.95 to read as follows:

§ 117.95 Holding and distribution of human food by-products for use in animal food.

(a) Human food by-products held for distribution as animal food without additional manufacturing/processing by the human food processor, as identified in § 507.12 of this chapter, must be held under conditions that will protect against contamination, including the following:

(1) Containers used to hold animal food before distribution must be designed, constructed

of appropriate material, cleaned, and maintained to prevent the contamination of animal food;

(2) Animal food held for distribution must be held in a way to prevent contamination from sources such as trash and garbage; and

(3) Labeling identifying the by-product by the common and usual name must be affixed to or accompany animal food.

(b) Shipping containers (for example, totes, drums, and tubs) and bulk vehicles used to distribute animal food must be inspected prior to use to ensure the container or vehicle will not contaminate the animal food.

PART 225--CURRENT GOOD MANUFACTURING PRACTICE FOR MEDICATED FEEDS

5. The authority citation for 21 CFR part 225 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360b, 371, 374.

6. In § 225.1, add paragraph (d) to read as follows:

§ 225.1 Current good manufacturing practice.

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(d) In addition, non-medicated feed is subject to part 507 of this chapter.

PART 500--GENERAL

7. The authority citation for 21 CFR part 500 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 353, 360b, 371, 379e.

8. Revise § 500.23 to read as follows:

§ 500.23 Thermally processed low-acid foods packaged in hermetically sealed containers.

Except as provided in § 507.5(b), the provisions of parts 507 and 113 of this chapter apply to the manufacturing, processing, or packing of low-acid foods in hermetically sealed containers, and intended for use as food for animals.

9. Add part 507 to read as follows:

PART 507--CURRENT GOOD MANUFACTURING PRACTICE AND HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS FOR FOOD FOR ANIMALS

Subpart A--General Provisions

Sec.

507.1 Applicability and status.

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507.5 Exemptions.

507.7 Requirements that apply to a qualified facility.

507.10 Applicability of subpart C to a facility solely engaged in the storage of packaged animal food that is not exposed to the environment.

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Sec.

507.14 Personnel.

507.17 Plant and grounds.

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507.20 ~~Sanitary facilities and controls.~~ Water supply and plumbing.

507.22 Equipment and utensils.

507.25 ~~Process and controls.~~ Plant operations.

507.2~~78~~ ~~Warehousing~~Holding and distribution.

507.28 Holding and distribution of human food by-products for use in animal food.

Subpart C--Hazard Analysis and Risk-Based Preventive Controls

Sec.

Authority: 21 U.S.C. 321, 331, 342, 350c, 350d note, 350g, 350g note, 371, 374; 42 U.S.C. 243, 264, 271.

Subpart A--General Provisions

§ 507.1 Applicability and status.

(a) The criteria and definitions in this part will apply in determining whether an animal food is adulterated:

(1) Within the meaning of section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act

in that the food has been manufactured under such conditions that it is unfit for food; or

(2) Within the meaning of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. The criteria and definitions in this part also apply in determining whether an animal food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

(b) The operation of a facility that manufactures, processes, packs, or holds animal food for sale in the United States if the owner, operator, or agent in charge of such facility is required to comply with and is not in compliance with section 418 of the Federal Food, Drug, and Cosmetic Act or subparts C, D, and F of this part and § 507.7 is a prohibited act under section 301(uu) of the Federal Food, Drug, and Cosmetic Act.

(c) Animal food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

~~(d) Animal food for sale in the United States must be manufactured, processed, packed, and held in accordance with the requirements in this part, subject to the exemptions in § 507.5. If a facility is required to comply with subpart B of this part and is also required to comply with subpart B of part 117 of this chapter because the facility manufactures, processes, packs, or holds human food, then the facility may choose to comply with the requirements in subpart B of part 117, instead of subpart B of part 507, as to the manufacturing, processing, packing, and holding of animal food at that facility. If a facility is required to comply with subpart C of part 507 and is also required to comply with subpart C of part 117 of this chapter, then the facility may choose to comply with the requirements in subpart C of part 117 as to the manufacturing, processing, packing, and holding of animal food at the facility, instead of subpart C of part 507, so long as~~

~~the food safety plan also addresses all hazards that are reasonably likely to occur in the animal food, including nutrient imbalances. In both instances, when applying the requirements of part 117 of this chapter to animal food, the term "food" in part 117 includes animal food.~~

§ 507.3 Definitions.

The definitions and interpretations contained in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this part. The following definitions also apply:

Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.

Affiliate means any facility that controls, is controlled by, or is under common control with another facility.

Animal food means food for animals other than man and includes pet food, animal feed, and raw materials and ingredients.

Batter means a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.

Blanching, except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.

Calendar day means every day shown on the calendar.

Critical control point means a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard

to an acceptable level.

Environmental pathogen means a ~~microorganism that is of animal or human health significance and is~~ pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food for animals may be contaminated and may result in foodborne illness if that animal food is not treated to significantly minimize or prevent the environmental pathogen. Environmental pathogen does not include the spores of pathogenic sporeformers.

Facility means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of 21 CFR part 1, subpart H.

Farm means farm as defined in § 1.227~~(b)~~ of this chapter.

FDA means the Food and Drug Administration.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Food-contact surfaces are those surfaces that contact animal food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. “Food-contact surfaces” include food-contact surfaces of utensils and equipment.

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed ~~by~~ on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities on a~~the~~ farm ~~on which they were grown or raised, or another farm under the same ownership~~. Harvesting does not include

activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Gathering, field coring, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm ~~or another farm under the same ownership~~ are examples of harvesting.

Hazard means any biological, chemical~~, physical, or~~ (including radiological), or physical agent that is reasonably likely to cause illness or injury in humans or animals ~~or humans~~ in the absence of its control.

~~Hazard reasonably likely to occur means a hazard for which a prudent person who manufactures, processes, packs, or holds food would establish controls because experience, illness data, scientific reports, or other information provides a basis to conclude that there is a reasonable possibility that the hazard will occur in the type of food being manufactured, processed, packed, or held in the absence of those controls.~~

Holding means storage of food~~. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators,~~ and ~~liquid storage tanks. For farms and farm mixed-type facilities, holding~~ also includes activities ~~traditionally~~ performed ~~by farms~~incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural ~~commodities grown or raised on the same farm or another farm under the same ownership,~~ commodity and breaking down pallets)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and

Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Known or reasonably foreseeable hazard means a biological, chemical (including radiological), or physical hazard that has the potential to be associated with the facility or the food.

Lot means the food produced during a period of time indicated by a specific code.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Microorganisms means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species having animal or human health significance. The term "undesirable microorganisms" includes those microorganisms that are of animal or human health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that

require the establishment to be registered.

Monitor means to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control and to produce an accurate record for use in verification.

Packaging (when used as a verb) means placing food into a container that directly contacts the food and that the consumer receives.

Packing means placing food into a container other than packaging the food~~. For farms~~ and ~~farm mixed-type facilities, packing~~ also includes activities ~~traditionally~~ performed ~~by farms to prepare raw agricultural commodities grown or raised on the same farm or another farm under the same ownership for storage and transport~~ incidental to packing a food (e.g., activities performed for the safe or effective packing of that food (such as sorting, culling and grading)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg).

Pathogen means a microorganism of public (human or animal) health significance.

Pest refers to any objectionable animals or insects including birds, rodents, flies, and larvae.

Plant means the building or establishment, or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of animal food.

Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food

manufacturing, processing, packing, or holding at the time of the analysis.

Qualified auditor means a person who is a qualified individual as defined in this part and has technical expertise obtained by a combination of training and experience appropriate to perform the auditing function as required by § 507.53(c)(2).

Qualified end-user, with respect to ~~an animal~~ food, means the consumer of the food (where the term does not include a business); or a restaurant or retail food establishment (as those terms are defined in § 1.227(b) of this chapter) that:

(1) Is located:

(i) In the same State as the qualified facility that sold the food to such restaurant or retail food establishment; or

(ii) Not more than 275 miles from such facility; and

(2) Is purchasing the food for sale directly to consumers at such restaurant or retail food establishment.

Qualified facility means (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) a facility that is a very small business as defined in this part, or a facility to which both of the following apply:

(1) During the 3-year period preceding the applicable calendar year, the average annual monetary value of the animal food manufactured, processed, packed, or held at such facility that is sold directly to qualified end-users (as defined in this part) during such period exceeded the average annual monetary value of the animal food sold by such facility to all other purchasers; and

(2) The average annual monetary value of all animal food sold during the 3-year period

preceding the applicable calendar year was less than $500,000, adjusted for inflation.

Qualified individual means a person who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA, or is otherwise qualified through job experience to develop and apply a food safety system.

Quality control operation means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated.

~~Reasonably foreseeable hazard means a potential biological, chemical, physical, or radiological hazard that may be associated with the facility, or the food.~~

Receiving facility means a facility that is subject to subpart C of this part and that manufactures/processes a raw material or ingredient that it receives from a supplier.

Rework means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

Safe moisture level is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, processing, packing, and holding. The safe moisture level for a food is related to its water activity (a_w). An a_w will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a_w will not support the growth of undesirable microorganisms.

Sanitize means to adequately treat cleaned food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of animal or human health significance, and in substantially reducing numbers of other undesirable microorganisms, but

without adversely affecting the product or its safety for animals or humans.

Should is used to state recommended or advisory procedures or identify recommended equipment. Should denotes non-binding guidance.

Significant hazard means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing/processing, packing, or holding of animal food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in an animal food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the control.

Significantly minimize means to reduce to an acceptable level, including to eliminate.

Small business means, for purposes of this part, a business employing fewer than 500 persons.

Subsidiary means any company that is owned or controlled directly or indirectly by another company.

Supplier means the establishment that manufactures/processes the food, raises the animal, or harvests the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a de minimis nature.

Validation means that element of verification focused on collecting and evaluating scientific and technical information to determine whether the food safety plan, when properly implemented, will effectively control the identified hazards.

Verification means those activities, other than monitoring, that establish the validity of the food safety plan and that the system is operating according to the plan.

~~Option 1 for Definition of "Very Small Business"~~

~~Very small business means, for purposes of this part, a business that has less than $500,000 in total annual sales of animal food, adjusted for inflation.~~

~~Option 2 for Definition of "Very Small Business"~~

~~Very small business means, for purposes of this part, a business that has less than $1,000,000 in total annual sales of animal food, adjusted for inflation.~~

~~Option 3 for Definition of "Very Small Business"~~

Very small business means, for purposes of this part, a business that has less than $2,500,000 in total annual sales of food for animals ~~food~~, adjusted for inflation.

Water activity (a_w) means a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

You means, for purposes of this part, the owner, operator, or agent in charge of a facility.

§ 507.5 Exemptions.

(a)(1) Except as provided by paragraph (a)(2) of this section, ~~T~~this part does not apply to establishments (including "farms" as defined in § 1.227~~(b)~~ of this chapter) that are not required to register under section 415 of the Federal Food, Drug, and Cosmetic Act.

(2) If a "farm" or "farm mixed-type facility" dries/dehydrates raw agricultural commodities to create a distinct commodity, subpart B of this part applies to the packaging, packing, and holding of the dried commodities. Compliance with this requirement may be achieved by complying with subpart B of this part or with the applicable requirements for packing and holding in part 112 of this chapter.

(b) Activities in animal food facilities that are regulated under, and are in compliance with, § 500.23 and part 113 of this chapter (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers) are exempt from subpart C of part 507 only with respect to those microbiological hazards regulated under part 113. The facilities must comply with subparts C and F of this part regarding all other potential hazards and must comply with subparts A and B of this part.

(c) Subpart C of this part does not apply to activities of a facility that are subject to section 419 of the Federal Food, Drug, and Cosmetic Act (Standards for Produce Safety).

(d) Except as provided in subpart D of this part, qualified facilities are exempt from subpart C of this part if they comply with the requirements in § 507.7.

(e) Subpart C of this part does not apply to on-farm packing or holding of animal food by a small or very small business if the only packing and holding activities subject to section 418 of the Federal Food, Drug, and Cosmetic Act that the business conducts are the following low-risk packing or holding activity/animal food combinations on animal food not grown, raised, or consumed on that farm mixed-type facility or another farm or farm mixed-type facility under the same ownership:

(1) Conveying, weighing, sorting, culling, or grading (incidental to storing):

(i) Grain (e.g., barley, corn, rice, oat, sorghum, triticale, wheat);

(ii) Oilseed (e.g., cottonseed, linseed, rapeseed, soybean, sunflower);

(iii) Grain or oilseed byproducts;

(iv) Forage (e.g., hay or ensiled material); or

(v) Other plants or plant byproducts (e.g., almond, peanut, or soybean hulls, citrus, other fruit including culled fruit, potatoes, or other vegetables including culled vegetables).

(2) Storing:

(i) Dried grain;

(ii) Dried oilseed;

(iii) Byproducts of dried grain or dried oilseed;

(iv) Forage; or

(v) Other plants or plant byproducts.

(3) Packing:

(i) Grain;

(ii) Oilseed;

(iii) Grain or oilseed byproducts;

(iv) Forage; or

(v) Other plants or plant byproducts.

(4) Mixing (incidental to packing or storing):

(i) Grain, whole; or

(ii) Forage.

(f) Subpart C does not apply to on-farm low-risk manufacturing/processing activities conducted by a small or very small business if the only manufacturing/processing activities subject to section 418 of the Federal Food, Drug, and Cosmetic Act that the business conducts consists of the following:

(1) When conducted on a farm mixed-typed facility's own raw agriculture commodities as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, (those grown or raised on that farm mixed-type facility or another farm/farm mixed-typed facility under the same ownership) for distribution into commerce:

(i) Cracking, crimping, or flaking:

(A) Grain (e.g., barley, corn, rice, oat, sorghum, triticale, wheat);

(B) Oilseed (e.g., cotton seed, linseed, rapeseed, soybean, sunflower); or

(C) Grain or oilseed byproducts.

(ii) Crushing, grinding, milling, pulverizing, or dry rolling:

(A) Grain;

(B) Oilseed;

(C) Grain or oilseed byproducts;

(D) Forage (e.g., hay or ensiled material); or

(E) Other plants or plant byproducts (e.g., such as almond, peanut, or soybean hulls, citrus, other fruit including culled fruit, potatoes, or other vegetables including culled vegetables).

(iii) Making silage.

(iv) Chopping or shredding hay.

(v) Extracting (mechanical) or wet rolling:

(A) Grain; or

(B) Oilseed.

(2) When conducted on animal food other than the farm mixed-typed facility's own raw agriculture commodities for distribution into commerce:

(i) Cracking, crimping, flaking, or shelling:

(A) Grain (e.g., barley, corn, rice, oat, sorghum, triticale, wheat);

(B) Oilseed (e.g., cotton seed, linseed, rapeseed, soybean, sunflower); or

(C) Grain or oilseed byproducts.

(ii) Crushing, grinding, milling, pulverizing, or dry rolling:

(A) Grain;

(B) Oilseed;

(C) Grain or oilseed byproducts;

(D) Forage (e.g., hay or ensiled material); or

(E) Other plants or plant byproducts (e.g., such as almond, peanut, or soybean hulls, citrus, other fruit including culled fruit, potatoes, or other vegetables including culled vegetables).

(iii) Making silage.

(iv) Chopping or shredding hay.

(v) Extracting (mechanical) or wet rolling:

(A) Grain; or

(B) Oilseed.

(vi) Labeling:

(A) Grain whole; or

(B) Oilseed whole.

(vii) Sifting, separating, or sizing:

(A) Grain;

(B) Oilseed;

(C) Grain or oilseed byproducts; or

(D) Other plants or plant byproducts.

(g) Subpart C of this part does not apply to facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further

distribution or processing.

(h) Subpart B of this part does not apply to the holding or transportation of one or more raw agricultural commodities as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

§ 507.7 Requirements that apply to a qualified facility.

(a) A qualified facility is exempt from subpart C of this part provided that for the calendar year in which it is to be considered a qualified facility, the facility has submitted to FDA documentation that:

(1) Demonstrates the facility is a qualified facility as defined in § 507.3. For the purpose of determining whether a facility satisfies the definition of qualified facility, the baseline year for calculating the adjustment for inflation is 2011; and

(2)(i) Demonstrates the owner, operator, or agent in charge of the facility has identified the potential hazards associated with the animal food being manufactured, processed, packed, or held at the facility, is implementing preventive controls to address the hazards, and is monitoring the performance of the preventive controls to ensure that such controls are effective; or

(ii) Demonstrates the facility is in compliance with state, local, county, or other applicable non-Federal food safety law. This documentation may include inspection reports, certification by an appropriate agency (such as a State department of agriculture), or other documentation deemed appropriate by FDA.

(b) The documentation required by paragraph (a) of this section must be submitted to FDA by any one of the following means:

(1) To submit electronically, go to http://www.access.fda.gov and follow the instructions. This Web site is available from wherever the Internet is accessible, including libraries, copy

centers, schools, and Internet cafes. FDA encourages electronic submission.

(2) To submit documents in a paper format or in an electronic format on a CD-ROM, mail these to the U.S. Food and Drug Administration, ATTN: Qualified Facility Coordinator, 10903 New Hampshire Ave., Silver Spring, MD 20993. We recommend that an owner, operator, or agent in charge of a facility submit by mail only if the facility does not have reasonable access to the Internet.

(c) The documentation required by paragraph (a) of this section must be:

(1) Submitted to FDA initially within 90 days of the applicable compliance date of this part; and

(2) Resubmitted at least every 2 years, or whenever there is a material change to the information described in paragraph (a) of this section. For the purpose of this section, a material change is one that changes whether or not a facility is a “qualified facility”.

(d) A qualified facility that does not submit documentation under paragraph (a)(2)(i) of this section must provide notification to consumers as to the name and complete business address (the street address, city, state, and ZIP code for domestic facilities, and comparable full address information for foreign facilities) of the facility where the animal food was manufactured or processed as follows:

(1) Such notification must appear in a prominent and conspicuous location on the label for animal food required to bear a package label under any other provision of the Federal Food, Drug, and Cosmetic Act.

(2) For animal food that is not required to bear a food packaging label, the notification must appear prominently and conspicuously, at the point of purchase, on a label, poster, sign, placard, or documents delivered contemporaneously with the food in the normal course of

business, or in an electronic notice, in the case of Internet sales.

(e) A qualified facility must maintain those records relied upon to support the documentation required by § 507.7(a)(2). These records are subject to the requirements of subpart F of this part.

§ 507.10 Applicability of subpart C to a facility solely engaged in the storage of packaged animal food that is not exposed to the environment.

(a) Subpart C of this part does not apply to a facility solely engaged in the storage of packaged animal food that is not exposed to the environment and does not require time/temperature control to ensure the safety of the animal food.

(b) A facility solely engaged in the storage of packaged animal food that is not exposed to the environment but requires time/temperature control is subject to the modified requirements in § 507.48.

§ 507.12 Applicability of this part to the holding and distribution of human food by-products for use in animal food.

(a) Except as provided by paragraph (b) of this section, the requirements of this part do not apply to by-products of human food production that are packed or held by that human food facility for distribution as animal food if:

(1) The human food processor is subject to and in compliance with subpart B of part 117 of this chapter, and in compliance with all applicable human food safety requirements of the Federal Food, Drug, and Cosmetic Act and implementing regulations; and

(2) The human food processor does not further manufacture/process the by-products intended for animal food.

(b) The animal food from by-products identified in paragraph (a) of this section must be

held and distributed by that facility in accordance with § 507.28 and § 117.95 of this chapter.

Subpart B--Current Good Manufacturing Practice

§ 507.14 Personnel.

(a) Plant management must take all reasonable measures and precautions to ensure that~~:~~

~~(1) Any person who, by his own acknowledgement, by medical examination, or by supervisory observation, is shown to have, or appears to have any illness, open skin lesion, or other source of abnormal microbial contamination by which there is a reasonable possibility of animal food, animal food-contact surfaces, or animal food-packaging materials becoming contaminated, is excluded from any operations which may be expected to result in such contamination until the condition is resolved;~~

~~(2) Personnel have been instructed to report such health conditions to their supervisors;~~

~~(3) All~~ all persons working in direct contact with animal food, animal food-contact surfaces, and animal food-packaging materials conform to hygienic practices ~~while on duty~~ to the extent necessary to protect against contamination of animal food. The methods for maintaining cleanliness include:

(~~i~~1) Maintaining adequate personal cleanliness;

(~~ii~~2) Washing hands thoroughly ~~(and sanitizing if necessary to protect against contamination with undesirable microorganisms)~~ in an adequate hand-washing facility ~~before starting work and at any other time when the hands may have become soiled or contaminated~~as necessary and appropriate to prevent contamination;

(~~iii~~3) Removing ~~all unsecured~~ or securing jewelry and other objects that might fall into animal food, equipment, or containers;

(~~iv~~4) Storing clothing or other personal belongings in areas other than where animal food

is exposed or where equipment or utensils are ~~washed~~cleaned; and

(~~v~~5) Taking any other necessary precautions to protect against contamination of animal food, animal food-contact surfaces, or animal food-packaging materials ~~with microorganisms or foreign substances~~.

(b) Personnel responsible for identifying sanitation failures or animal food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe animal food. Animal food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.

(c) Responsibility for ensuring compliance by all personnel with all requirements of this subpart must be clearly assigned to competent supervisory personnel.

§ 507.17 Plant and grounds.

(a) The grounds ~~about~~ surrounding an animal food plant under the control of the operator must be kept in a condition that will protect against the contamination of animal food. ~~The methods for adequate maintenance~~ Maintenance of grounds must include:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests;

(2) Maintaining ~~roads~~driveways, yards, and parking ~~lots~~ areas so that they do not constitute a source of contamination in areas where animal food is exposed;

(3) Adequately draining areas that may contribute to contamination of animal food ~~by seepage, foot-borne filth, or providing a breeding place for pests~~; and

(4) Treating and disposing of waste so that it does not constitute a source of contamination in areas where animal food is exposed. ~~If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraph (a)(1) through (a)(3) of this section, care must be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of animal food contamination.~~

(b) ~~The plant's b~~Buildings~~, and~~ structures, fixtures, and other physical facilities of the plant must be suitable in size, construction, and design to facilitate cleaning, maintenance, and pest control ~~sanitary operations for animal food-production purposes (i.e., manufacturing, processing, packing, and holding). The plant must:~~

~~(1) Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe animal food.~~

~~(2) Permit the taking of proper precautions~~to reduce the potential for contamination of animal food, animal food-contact surfaces, ~~or~~and animal food-packaging materials. This includes: ~~with microorganisms, chemicals, filth, and other extraneous material. The potential for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur, by one or more of the following means: Location, time, partition, air flow, enclosed systems, or other effective means.~~.

~~(3) Permit the taking of proper precautions to protect animal food in outdoor bulk vessels by any effective means, including:~~

~~(i) Using protective coverings;~~

~~(ii) Controlling areas over and around the vessels to eliminate harborages for pests;~~

~~(iii) Checking on a regular basis for pests and pest infestation; and~~

~~(iv) Skimming fermentation vessels, as necessary.~~

(1) Providing adequate space between equipment, walls, and stored materials to permit employees to perform their duties and to allow cleaning and maintenance of equipment;

(~~4~~2) Being constructed in ~~such~~ a manner ~~that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair;~~ such that drip or condensate from fixtures, ducts, and pipes does not serve as a source of contamination;~~e food, animal food-contact surfaces, or animal food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating animal food, animal food-contact surfaces, or animal food-packaging materials.~~

(3) Providing adequate ventilation or control equipment to minimize vapors (for example, steam) and fumes in areas where they may contaminate animal food; and locating and operating fans and other air-blowing equipment in a manner that minimizes the potential for contaminating animal food.

~~(5)~~(4) Provide~~e~~ing adequate lighting in hand-washing areas, toilet rooms, areas where animal food is ~~examined,~~ received, manufactured/processed, packed, or stored, and areas where equipment or utensils are cleaned; ~~and~~

(5) ~~p~~Provide~~e~~ing safety-type light bulbs, fixtures, and skylights, or other glass items suspended over exposed animal food in any step of preparation, ~~or otherwise~~to protect against animal food contamination in case of glass breakage; and

(6) Protecting animal food stored outdoors in bulk by any effective means, including:

(i) Using protective coverings;

(ii) Controlling areas over and around the bulk animal food to eliminate harborages for pests; and

(iii) Checking on a regular basis for pests and pest infestation.

~~(6) Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate animal food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating animal food, animal food-packaging materials, and animal food-contact surfaces.~~

~~(7) Provide, where necessary, adequate screening or other protection against pests.~~

§ 507.19 Sanitation~~ry operation~~.

(a) Buildings, structures, fixtures, and other physical facilities of the plant must be ~~maintained in a sanitary condition and must be~~ kept clean and in good repair ~~sufficient~~ to prevent animal food from becoming contaminated~~adulterated~~.

(b) Animal food-contact and non-contact surfaces ~~Cleaning and sanitizing~~ of utensils and equipment must be ~~conducted in a manner that~~ cleaned and maintained and utensils and equipment stored as necessary and appropriate to protects against contamination of animal food, animal food-contact surfaces, or animal food-packaging materials. When necessary, equipment must be disassembled for thorough cleaning. In addition:

(1) When it is necessary to wet-clean animal food-contact surfaces used for manufacturing/processing, or holding low-moisture animal food, the surfaces must be thoroughly dried before subsequent use.

(2) In wet processing, when cleaning and sanitizing is necessary to protect against the introduction of undesirable microorganisms into animal food, all animal food-contact surfaces~~,~~

~~or~~ must be cleaned and sanitized before use and after any interruption during which the animal food contact surfaces may have become contaminated.

(~~b~~c) Cleaning compounds and sanitizing agents must be ~~free from undesirable microorganisms and must be~~ safe and adequate under the conditions of use. ~~Compliance with this requirement may be verified by any effective means, including purchase of these substances under a supplier's guarantee or certification or examination of these substances for contamination.~~

(~~c~~d) The following applies to toxic materials:

(1) Only the following toxic materials may be used or stored in a plant where animal food is manufactured/processed or exposed:

(i) Those required to maintain clean and sanitary conditions;

(ii) Those necessary for use in the plant's operations~~laboratory testing procedures~~;

(iii) Those necessary for plant and equipment maintenance and operation; and

(iv) Those necessary for use in laboratory testing procedures ~~the plant's operations~~.

(2) Toxic materials described in paragraph (d)(1) of this section (for example cleaning compounds, sanitizing agents, and pesticide chemicals) must be identified, ~~held~~used, and stored in a manner that protects against contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

(~~d~~e) Effective measures must be taken to exclude pests from the manufacturing~~,~~ /processing, packing, and holding areas and to protect against the contamination of animal food ~~on the premises~~ by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of animal food, animal food-contact surfaces, and animal food-packaging materials.

~~(c) All animal food-contact surfaces, including utensils and animal food-contact surfaces of equipment, must be cleaned as frequently as necessary to protect against contamination of animal food.~~

~~(1) Animal food-contact surfaces used for manufacturing, processing or holding low-moisture animal food must be in a clean, dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they must, when necessary, be sanitized and thoroughly dried before subsequent use.~~

~~(2) In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into animal food, all animal food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the animal food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and animal food-contact surfaces of the equipment must be cleaned and sanitized as necessary.~~

~~(3) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and must be handled, dispensed, used,~~ (f) Trash and garbage must be conveyed, stored, and disposed of in a ~~manner~~way that protects against contamination of animal food, animal food-contact surfaces, ~~or~~ animal food-packaging materials, water supplies, and ground surfaces, and minimizes the potential for the trash and garbage to become an attractant and harborage or breeding place for pests.

~~(f) Non-animal food-contact surfaces of equipment used in the operation of an animal food plant should be cleaned in a manner and as frequently as necessary to protect against contamination of animal food, animal food-contact surfaces, and animal food-packaging materials.~~

~~(g) Cleaned and sanitized portable equipment with animal food-contact surfaces and utensils should be stored in a location and manner that protects animal food-contact surfaces from contamination.~~

§ 507.20 ~~Sanitary facilities and controls~~Water supply and plumbing.

(a) The water supply must be ~~sufficient~~adequate for the operations ~~intended~~ and must be derived from ~~an adequate~~a suitable source. ~~Any water that contacts animal food, animal food-contact surfaces, or animal food-packaging materials must be safe and of adequate sanitary quality.~~ Running water at a suitable temperature, and under suitable pressure as needed, must be provided in all areas where required for the manufacturing/processing of animal food, for the cleaning of equipment, utensils, and animal food-packaging materials, or for employee ~~sanitary facilities~~hand-washing facilities. Water that contacts animal food, animal food-contact surfaces, or animal food-packaging materials must be safe for its intended use. Water may be reused for washing, rinsing, or conveying animal food if it does not increase the level of contamination of the animal food.

(b) Plumbing must be ~~of adequate size and design and adequately~~designed, installed, and maintained to:

(1) Carry ~~sufficient~~ adequate quantities of water to required locations throughout the plant;

(2) Properly convey sewage and liquid disposable waste from the plant;

(3) Avoid ~~constituting~~being a source of contamination to animal food, animal food-contact surfaces, or animal food-packaging materials, water supplies, equipment, or utensils ~~or~~, and avoid creating an unsanitary condition;

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type

cleaning or where normal operations release or discharge water or other liquid waste on the floor; and

(5) ~~Provide~~Ensure that there is ~~not~~no backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for animal food or animal food manufacturing/processing.

(c) Sewage must be disposed of through an adequate sewerage system or through other adequate means.

(d) Each plant must provide its employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

(e) Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of animal food, animal food-contact surfaces, or animal food-packaging materials~~, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature~~.

~~(f) Rubbish must be conveyed, stored, and disposed of in a way to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of animal food, animal food-contact surfaces, animal food-packaging materials, water supplies, and ground surfaces.~~

§ 507.22 Equipment and utensils.

(a) The following apply to plant equipment and utensils:

(1) All plant equipment and utensils must be designed and of such material and workmanship to be adequately cleanable, and must be properly maintained;

(2) The design, construction, and use of equipment and utensils must preclude the

~~adulteration~~contamination of animal food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants;

(3) ~~All e~~Equipment should be installed and maintained in such a way as to facilitate the cleaning of the equipment and ~~all~~ adjacent spaces;

(4) Animal food-contact surfaces must be ~~made~~:

(i) Made of materials that ~~resist corrosion when in contact with animal food;~~

~~(5) Animal food-contact surfaces must be made of nontoxic materials and designed to~~ withstand the environment of their ~~intended~~ use and the action of animal food, and, if applicable, the action of cleaning compounds and sanitizing agents; ~~and~~

(ii)~~(6) Animal food-contact surfaces must be maintained~~ Made of nontoxic materials; and

(iii) Maintained to protect animal food from being contaminated.

~~(b) Seams on animal food-contact surfaces must be maintained so as to minimize accumulation of food particles, dirt, and organic matter, and thus minimize the opportunity for growth of microorganisms.~~

~~(c)~~(5) Equipment in the animal food manufacturing ~~or handling~~/processing area that does not come into contact with animal food must be designed and constructed in such a way that it can be kept in a clean condition.

(~~d~~b) Holding, conveying, and manufacturing/processing systems, including gravimetric, pneumatic, closed, and automated systems, must be ~~of a design~~designed, constructed, and ~~construction that enables them to be~~ maintained in ~~an appropriate sanitary condition.~~a way that does not contaminate animal food.

(~~e~~c) Each freezer and cold storage compartment used to ~~store and~~ hold animal food ~~capable of supporting growth of microorganisms~~ must be fitted with an ~~indicating~~

~~thermometer,~~accurate temperature ~~measuring~~ monitoring device~~, or temperature-recording device installed to show the temperature accurately within the compartment~~.

(~~f~~d) Instruments and controls used for measuring, regulating, or recording temperatures, pH, aw, or other conditions that control or prevent the growth of undesirable microorganisms in animal food must be accurate ~~and,~~ precise ~~and,~~ adequately maintained, and adequate in number for their designated uses.

(~~g~~e) Compressed air or other gases mechanically introduced into animal food or used to clean animal food-contact surfaces or equipment must be ~~treated~~used in such a way that animal food is not contaminated.

§ ~~-~~ 507.25 ~~Processes and controls~~Plant operations.

(a) Plant management must ensure that:

(1) All operations in the manufacturing~~, /~~processing, packing, and holding of animal food (including operations directed to receiving, inspecting, transporting, and segregating) are conducted in accordance with ~~adequate sanitation principles~~the current good manufacturing practice requirements of this subpart;

(2) Containers holding animal food, including raw materials, ~~or~~ ingredients ~~are labeled to~~, or rework, accurately identify the contents;

(3) The labeling for the finished animal food product contains ~~the specific~~ information and instructions ~~needed so the food can be~~ for safely ~~used~~using the product for the intended animal species;

(4) ~~Appropriate quality control operations are employed so that animal~~Animal food-packaging materials are safe and suitable;

(5) The overall ~~sanitation~~cleanliness of the plant is under the supervision of one or more

competent individuals assigned responsibility for this function;

(6) ~~All r~~Reasonable precautions are taken so that ~~production procedures~~plant operations do not contribute to contamination ~~from any source~~of animal food, animal food-contact surfaces, and animal food packaging materials;

(7) Chemical, microbial, or extraneous-material testing procedures are used where necessary to identify sanitation failures or possible animal food contamination; and

(8) ~~All a~~Animal food that has become contaminated to the extent that it is adulterated is rejected, disposed of, or if permissible, treated or processed to eliminate the adulteration. If disposed of, it must be done in a manner that protects against the contamination of other animal food; and

(9) All animal food manufacturing/processing, packing, and holding is conducted under such conditions and controls as are necessary to minimize the potential for the growth of undesirable microorganisms or for the contamination of animal food.

(b) Raw materials and ingredients:

(1) Must be inspected ~~and segregated or otherwise handled as necessary~~ to ensure that they are ~~clean and~~ suitable for manufacturing/processing into animal food and must be ~~stored~~handled under conditions that will protect against contamination and minimize deterioration. In addition:

(i) ~~Raw materials must be washed or cleaned as necessary to remove soil or other contamination;~~

~~(ii) Water used for washing, rinsing, or conveying animal food must be safe and of adequate sanitary quality;~~

~~(iii) Water may be reused for washing, rinsing, or conveying animal food if it does not~~

~~increase the level of contamination of the animal food; and~~

~~(iv)~~ Shipping ~~C~~containers (for example, totes, drums, and tubs) and ~~carriers of~~bulk vehicles holding raw materials and ingredients ~~should~~must be inspected ~~on~~upon receipt to ~~ensure that their condition has not contributed to~~determine whether contamination or deterioration of animal food~~.~~ has occurred;

~~(2) Must not contain levels of microorganisms that may render the food injurious to the health of animals or humans, or they must be treated (e.g., heat) during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated;~~

~~(3)~~ (ii) Raw materials must be cleaned as necessary to minimize soil or other contamination; and

(iii) Raw materials and ingredients must be stored under conditions that will protect against contamination and deterioration.

(2) Susceptible to contamination with ~~aflatoxin~~mycotoxins or other natural toxins must ~~comply with current FDA regulations for poisonous or deleterious substances before these materials or ingredients are incorporated into finished animal food~~be evaluated and used in a manner that does not result in animal food that can cause injury or illness to animals or humans;

(3~~4~~) ~~Including~~ And all rework, must be held in ~~bulk, or in~~ containers designed and constructed in a way that protects against contamination, and must be held ~~at a~~under conditions, e.g., appropriate temperature and relative humidity~~-~~, that will minimize the potential for growth of undesirable microorganisms and in a manner that prevents the animal food from becoming adulterated~~. Material scheduled for rework must be identified as such;~~; and

(~~5~~4) If frozen, must be kept frozen. If thawing is required prior to use, it must be done in a manner that ~~prevents the raw materials and ingredients from becoming adulterated;~~

~~and~~minimizes the potential for the growth of undesirable microorganisms.

~~(6) Whether liquid or dry, received and stored in bulk form must be held in a manner that protects against contamination.~~

(c) For the purposes of manufacturing/processing operations, the following apply:

(1) ~~Equipment, utensils, and finished animal food containers must be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. When necessary, equipment must be taken apart for thorough cleaning;~~

~~(2) All animal food manufacturing, processing, packing, and holding must be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms or for the contamination of animal food;~~

~~(3)~~ Animal food must be maintained under conditions, e.g., appropriate temperature and relative humidity, that will minimize the potential for ~~that can support the rapid~~ growth of undesirable microorganisms ~~must be held at temperatures that will~~ and prevent the animal food from becoming adulterated during manufacturing~~,~~/processing, packing, and holding;

(~~4~~2) Measures taken ~~to destroy~~during manufacturing/processing, packing, and holding of animal food to significantly minimize or prevent the growth of undesirable microorganisms~~, such as sterilizing, irradiating, pasteurizing, cooking~~ (for example, heat treating, freezing, refrigerating, irradiating, controlling pH, or controlling aw~~,~~) must be adequate ~~under the conditions of manufacture, handling, and distribution~~ to prevent adulteration of animal food ~~from being adulterated~~;

(~~5~~3) Work-in-process and rework must be handled in such a ~~manner~~way that ~~protects~~it is protected against contamination and the growth of undesirable microorganisms;

~~(6) Effective measures must be taken to protect finished animal food from contamination~~

~~by raw materials, ingredients, or refuse. When raw materials, ingredients, or refuse are unprotected, they must not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in contaminated animal food. Animal food transported by conveyor must be protected against contamination as necessary;~~

~~(7) Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or animal food must be constructed, handled, and maintained during manufacturing, processing, packing, or holding in a manner that protects against contamination of animal food;~~

~~(8) Effective measures must be taken to protect against the inclusion of metal or other extraneous material in animal food;~~

~~(9) Adulterated animal food, raw materials, and ingredients must be disposed of in a manner that protects against the contamination of other animal food or, if the adulterated animal food, raw materials, or ingredients are capable of being reconditioned, they must be reconditioned using a method that has been proven to be effective;~~

~~(10)~~ (4) Steps such as ~~washing, peeling, trimming,~~ cutting, ~~sorting and inspecting, mashing, dewatering, cooling, shredding, extruding,~~ drying, defatting, ~~and forming~~ grinding, mixing, extruding, pelleting, and cooling, must be performed in a way that protects animal food against contamination~~. Animal food should be protected from contaminants that may drip, drain, or be drawn into the animal food;~~;

~~(11) Heat blanching, when required in the preparation of animal food, should be effected by heating the animal food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the animal food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be~~

~~minimized by the use of adequate operating temperatures and by periodic cleaning;~~

~~(12) Batters, breading, sauces, gravies, dressings, and other similar preparations must be treated or maintained in such a manner that they are protected against contamination;~~

(~~13~~5) Filling, assembling, packaging, and other operations must be performed in such a way that the animal food is protected against contamination and growth of undesirable microorganisms;

(~~14~~6) Animal food~~, including dry mixes, nuts, intermediate moisture animal food, and dehydrated animal food,~~ that relies on the control of aw for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe moisture level;

(~~15~~7) Animal food that relies principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at the appropriate pH; and

(~~16~~8) When ice is used in contact with animal food, it must be made from water that is safe~~ and of adequate sanitary quality,~~ and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this ~~part~~subpart.

§ 507.27~~28 Warehousing~~ Holding and distribution.

~~Storage and transportation of animal food must be conducted under conditions that will protect against biological, chemical, physical, and radiological contamination of animal food as well as against deterioration of the animal food and the container.~~

(a) Animal food held for distribution must be held under conditions that will protect against contamination and minimize deterioration, including the following:

(1) Containers used to hold animal food before distribution must be designed, constructed of appropriate material, cleaned, and maintained to prevent the contamination of animal food;

(2) Animal food held for distribution must be held in a way that prevents contamination

from sources such as trash and garbage; and

(3) Labeling identifying the product by the common and usual name must be affixed to or accompany the animal food.

(b) Shipping containers (for example, totes, drums, and tubs) and bulk vehicles used to distribute animal food must be inspected prior to use to ensure the container or vehicle will not contaminate the animal food.

(c) Animal food returned from distribution must be assessed for animal food safety to determine the appropriate disposition. Returned animal food must be identified as such and segregated until assessed.

(d) Unpackaged or bulk animal food must be held in a manner that does not result in cross contamination with other animal food.

§ 507.28 Holding and distribution of human food by-products for use as animal food.

(a) Human food by-products held for distribution as animal food must be held under conditions that will protect against contamination, including the following:

(1) Containers used to hold animal food before distribution must be designed, constructed of appropriate material, cleaned, and maintained to prevent the contamination of animal food;

(2) Animal food held for distribution must be held in a way to prevent contamination from sources such as trash and garbage; and

(3) Labeling identifying the product by the common and usual name must be affixed to or accompany animal food.

(b) Shipping containers (for example, totes, drums, and tubs) and bulk vehicles used to distribute animal food must be inspected prior to use to ensure the container or vehicle will not contaminate the animal food.

Subpart C--Hazard Analysis and Risk-Based Preventive Controls

§ 507.3130 Requirement for af Food safety plan.

(a) The owner, operator, or agent in charge of a facilityYou must prepare, or have prepared, and implement a written food safety plan.

(b) The written food safety planOne or more qualified individuals must be prepared by (or its preparation overseen by) a qualified individual the preparation of, the food safety plan.

(c) The written food safety plan must include:

(1) The written hazard analysis as required by § 507.33(a)(2);

(2) The written preventive controls as required by § 507.36(b);

(3) The written supplier program as required by § 507.37(a)(2).

(43) The written recall plan as required by § 507.38(a)(1);

(54) The written procedures and the frequency with which these procedures will be conducted for monitoring the performanceimplementation of the preventive controls as required by § 507.39;40(a)(1);

(65) The written corrective action procedures as required by § 507.42(a)(1); and

(76) The written verification procedures and the frequency with which they will be performed as as required by § 507.49(b)5.

(d) The food safety plan required by this section is a record that is subject to the requirements of subpart F of this part.

§ 507.33 Hazard analysis.

(a) The owner, operator, or agent in charge of a facilityYou must identify:

(1) Identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of animal food

manufactured~~, /~~/processed, packed, or held at ~~the~~your facility to determine whether there are significant hazards ~~that are reasonably likely to occur;~~ and

(2) D~~d~~evelop a written hazard analysis.

(b) The hazard ~~analysis~~identification must consider ~~hazards that may occur naturally or may be unintentionally introduced including~~:

(1) Hazards that include:

(~~1~~i) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other ~~microorganisms of animal or human health significance~~pathogens;

(~~2~~ii) Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and nutrient imbalances; and

(~~3~~iii) Physical hazards; and

~~(4) Radiological hazards.~~

(2) Hazards that may be present in the animal food for any of the following reasons:

(i) The hazard occurs naturally;

(ii) The hazard may be unintentionally introduced; or

(iii) The hazard may be intentionally introduced for purposes of economic gain.

(c)(1) The hazard analysis must ~~contain~~include an evaluation of the hazards identified in paragraph (b) of this section to ~~determine whether the hazards are reasonably likely to occur, including an assessment of~~assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.

(2) The hazard evaluation required by paragraph (c)(1) of this section must include an

evaluation of environmental pathogens whenever an animal food is exposed to the environment prior to packaging and the packaged animal food does not receive a treatment that would significantly minimize the pathogen.

(d) The hazard ~~analysis~~evaluation must consider the effect of the following on the safety of the finished animal food for the intended animal:

(1) The formulation of the animal food;

(2) The condition, function, and design of the facility and equipment;

(3) Raw materials and ingredients;

(4) Transportation practices;

(5) Manufacturing/processing procedures;

(6) Packaging activities and labeling activities;

(7) Storage and distribution;

(8) Intended or reasonably foreseeable use;

(9) Sanitation, including employee hygiene; and

(10) Any other relevant factors.

§ 507.36 Preventive controls ~~for hazards that are reasonably likely to occur~~.

~~For hazards identified in the hazard analysis as reasonably likely to occur:~~

(a) ~~The owner, operator, or agent in charge of a facility~~(1) You must identify and implement preventive controls~~, including at critical control points, if any,~~ to provide assurances that ~~hazards identified in the hazard analysis as reasonably likely to occur~~significant hazards will be significantly minimized or prevented and the animal food manufactured, processed, packed, or held by ~~such~~your facility will not be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act; and

(2) Preventive controls required by paragraph (a)(1) of this section include, as appropriate to the facility and animal food:

(i) Controls at critical control points (CCPs), if there are any CCPs; and

(ii) Controls, other than those at CCPs, that are also appropriate for animal food safety.

(b) Preventive controls must be written.

(c) Preventive controls ~~must~~ include, as appropriate to the facility and animal food:

(1) Process controls include procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, irradiating, and refrigerating animal food. Process controls must include, as appropriate to the applicable control:

(~~1~~i) Parameters associated with the control of the hazard~~, such as parameters associated with heat processing, irradiating, and refrigerating animal foods~~; and

(~~2~~ii) The maximum or minimum value, or combination of values, to which any biological, chemical, or physical~~, or radiological~~ parameter must be controlled to significantly minimize or prevent a significant hazard ~~that is reasonably likely to occur~~.

~~(d) Preventive controls must include, as appropriate:~~

~~(1) Process controls that include those procedures, practices, and processes performed on an animal food during manufacturing/processing that are employed to significantly minimize or prevent hazards that are reasonably likely to occur;~~

(2) Sanitation controls include procedures, practices and processes to ensure that the facility is maintained in a sanitary condition adequate~~:~~

~~(i) Where necessary~~ to significantly minimize or prevent hazards ~~that are reasonably likely to occur~~ such as environmental pathogens and biological hazards due to employee handling. Sanitation controls must include as appropriate to the facility and the animal food,

procedures, practices, and processes for the:

(~~A~~i) Cleanliness of animal food-contact surfaces, including animal food-contact surfaces of utensils and equipment; and

(~~B~~ii) Prevention of cross-contamination from insanitary objects and from personnel to animal food, animal food packaging material, and other animal food-contact surfaces and from raw product to processed product.

~~(ii) The owner, operator, or agent in charge must take action to correct, in a timely manner, conditions and practices that are not consistent with the procedures in paragraph (d)(2)(i)(A) or (d)(2)(i)(B) of this section.~~

~~(iii) The owner, operator, or agent in charge of the facility is not required to follow the corrective actions described in § 507.42(a) and (b) when the owner, operator, or agent in charge of a facility takes action, in accordance with paragraph (d)(2)(ii) of this section, to correct conditions and practices that are not consistent with the procedures in paragraph (d)(2)(i)(A) or (d)(2)(i)(B) of this section.~~

~~(iv) All corrective actions taken in accordance with paragraph (d)(2)(ii) of this section must be documented in records that are subject to verification in accordance with § 507.45(b)(2) and records review in accordance with § 507.45(c)(1)(i) and (c)(2).~~

(3) Supplier controls that include the supplier program as required by § 507.37;

(~~3~~4) A recall plan as required by § 507.38; and

(~~4~~5) ~~Any~~ O~~o~~ther preventive controls that include any procedures, practices, and processes necessary to satisfy the requirements of paragraph (a) of this section. Examples of other controls include hygiene training and other current good manufacturing practices.

~~(e)(1) Except as provided by paragraph (e)(2) of this section, the preventive controls~~

~~required under this section are subject to:~~

~~(i) Monitoring as required by § 507.39;~~

~~(ii) Corrective actions as required by § 507.42; and~~

~~(iii) Verification as required by § 507.45.~~

~~(2) The recall plan established in § 507.38 is not subject to the requirements of paragraph (e)(1) of this section.~~

§ 507.37 Supplier program.

(a)(1)(i) Except as provided in paragraph (a)(1)(ii) of this section, the receiving facility must establish and implement a risk-based supplier program for those raw materials and ingredients for which the receiving facility has identified a significant hazard when the hazard is controlled before receipt of the raw material or ingredient.

(ii) The receiving facility is not required to establish and implement a supplier program for raw materials and ingredients for which:

(A) There are no significant hazards;

(B) The preventive controls at the receiving facility are adequate to significantly minimize or prevent each of the significant hazards; or

(C) The receiving facility relies on its customer to control the hazard and annually obtains from its customer written assurance that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard.

(2) The supplier program must be written.

(3) The supplier program must include:

(i) Verification activities, as appropriate to the hazard, and documentation of these

activities, to ensure raw materials and ingredients are received only from suppliers approved for control of the hazard(s) in that raw material or ingredient (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or ingredients the receiving facility subjects to adequate verification activities before acceptance for use); and

(ii) Verification activities, as appropriate to the hazard, and documentation of these activities, as required by paragraph (b) of this section, to verify that:

(A) The hazard is significantly minimized or prevented;

(B) The incoming raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act; and

(C) The incoming raw material or ingredient is produced in compliance with the requirements of applicable FDA food safety regulations.

(4) When supplier verification activities are required under paragraph (c) of this section for more than one type of hazard in an animal food, the receiving facility must conduct the verification activity or activities appropriate for each of those hazards.

(5) For some hazards, in some situations under paragraph (b) it will be necessary to conduct more than one verification activity and/or to increase the frequency of one or more verification activities to provide adequate assurances that the hazard is significantly minimized or prevented.

(b) In determining and documenting the appropriate verification activities, the receiving facility must consider the following:

(1) The hazard analysis, including the nature of the hazard, applicable to the raw material and ingredients;

(2) Where the preventive controls for those hazards are applied for the raw material and

ingredients such as at the supplier or the supplier's supplier;

(3) The supplier's procedures, processes, and practices related to the safety of the raw material and ingredients;

(4) Applicable FDA food safety regulations and information relevant to the supplier's compliance with those regulations, including an FDA warning letter or import alert relating to the safety of the animal food;

(5) The supplier's food safety performance history relevant to the raw materials or ingredients that the receiving facility receives from the supplier, including available information about results from testing raw materials or ingredients for hazards, audit results relating to the safety of the animal food, and responsiveness of the supplier in correcting problems; and

(6) Any other factors as appropriate and necessary. Examples of factors that a receiving facility may determine are appropriate and necessary are storage and transportation practices.

(c)(1) Except as provided in paragraph (c)(2) or (c)(3) of this section, the receiving facility must conduct and document one or more of the following supplier verification activities determined by the receiving facility under paragraph (b) of this section, for each supplier before using the raw material or ingredient and periodically thereafter:

(i) Onsite audits;

(ii) Sampling and testing of the raw material or ingredient, which may be conducted by either the supplier or receiving facility;

(iii) Review by the receiving facility of the supplier's relevant food safety records; or

(iv) Other appropriate supplier verification activities based on the risk associated with the ingredient and the supplier.

(2)(i) Except as provided by paragraph (c)(2)(ii) of this section, when a hazard in a raw

material or ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, the receiving facility must have documentation of an onsite audit of the supplier before using the raw material or ingredient from the supplier and at least annually thereafter.

(ii) The requirements of paragraph (c)(2)(i) of this section do not apply if the receiving facility documents its determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled.

(3) If a supplier is a qualified facility as defined by § 507.3, the receiving facility need not comply with paragraphs (c)(1) and (c)(2) of this section if the receiving facility:

(i) Documents, at the end of each calendar year, that the supplier is a qualified facility as defined by § 507.3; and

(ii) Obtains written assurance, at least every 2 years, that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act. The written assurance must include a brief description of the processes and procedures that the supplier is following to ensure the safety of the animal food.

(4) If a supplier is a farm that is not subject to the requirements established in part 112 of this chapter in accordance with § 112.4 regarding the raw material or ingredient that the receiving facility receives from the farm, the receiving facility does not need to comply with paragraphs (c)(1) and (c)(2) of this section if the receiving facility:

(i) Documents, at the end of each calendar year, that the raw material or ingredient provided by the supplier is not subject to part 112 of this chapter; and

(ii) Obtains written assurance, at least every 2 years, that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

(d)(1) An onsite audit of a supplier must be performed by a qualified auditor;

(2) If the raw material or ingredient at the supplier is subject to one or more FDA food safety regulations, an onsite audit must consider such regulations and include a review of the supplier's written plan (e.g., HACCP plan or other food safety plan), if any, including its implementation, for the hazard being audited.

(e)(1) Instead of an onsite audit, a receiving facility may rely on the results of an inspection of the supplier by FDA or, for a foreign supplier, by FDA or the food safety authority of a country whose food safety system FDA has recognized as comparable or has determined to be equivalent to that of the United States, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted; and

(2) For inspections conducted by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent, the animal food that is the subject of the onsite audit must be within the scope of the official recognition or equivalence determination, and the foreign supplier must be in, and under the regulatory oversight of, such country.

(f) If the owner, operator, or agent in charge of a receiving facility determines through auditing, verification testing, relevant consumer, customer, or other complaints, or otherwise that the supplier is not controlling hazards that the receiving facility has identified as significant, the receiving facility must take and document prompt action in accordance with § 507.42 to ensure

that raw materials or ingredients from the supplier do not cause animal food that is manufactured or processed by the receiving facility to be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

(g) The receiving facility must document the following in records and review such records in accordance with § 507.49(a)(4):

(1) The written supplier program;

(2) Documentation of the appropriate verification activities;

(3) The annual written assurance that a receiving facility's customer who is controlling a significant hazard has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard;

(4) Documentation demonstrating that products are received only from approved suppliers;

(5) Documentation of an onsite audit. This documentation must include:

(i) Documentation of audit procedures;

(ii) The dates the audit was conducted;

(iii) The conclusions of the audit;

(iv) Corrective actions taken in response to significant deficiencies identified during the audit; and

(v) Documentation that the audit was conducted by a qualified auditor.

(6) Records of sampling and testing. These records must include:

(i) Identification of the raw material or ingredient tested (including lot number, as appropriate) and the number of samples tested;

(ii) Identification of test(s) conducted, including the analytical method(s) used;

(iii) The date(s) on which the test(s) were conducted;

(iv) The results of the testing;

(v) Corrective actions taken in response to detection of hazards; and

(vi) Information identifying the laboratory conducting the testing.

(7) Records of the review by the receiving facility of the supplier's relevant food safety records. These records must include:

(i) The date(s) of review;

(ii) Corrective actions taken in response to significant deficiencies identified during the review; and

(iii) Documentation that the review was conducted by a qualified individual.

(8) Records of other appropriate supplier verification activities based on the risk associated with the ingredient.

(9) Documentation of any determination that verification activities other than an onsite audit, and/or less frequent onsite auditing of a supplier, provide adequate assurance that the hazards are controlled;

(10) Documentation of an alternative verification activity for a supplier that is a qualified facility, including:

(i) The documentation that the supplier is a qualified facility as defined by § 507.3; and

(ii) The written assurance that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

(11) Documentation of an alternative verification activity for a supplier that is a farm that supplies a raw material or ingredient that is not subject to part 112 of this chapter, including:

(i) The documentation that the raw material or ingredient provided by the supplier is not subject to part 112 of this chapter; and

(ii) The written assurance that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

(12) Evidence of an inspection of the supplier by FDA or the food safety authority of another country.

(13) Documentation of actions taken with respect to supplier non-conformance.

§ 507.38 Recall plan ~~for animal food with a hazard that is reasonably likely to occur~~.

(a) For an animal food with a significant hazard you must~~The owner, operator, or agent in charge of a facility must~~:

(1) Establish~~develop~~ a written recall plan for the animal food ~~with a hazard that is reasonably likely to occur~~; and

(2) ~~a~~Assign responsibility for performing all ~~actions~~procedures in the recall plan.

(b) The written recall plan must include procedures ~~for~~that describe the steps to perform the following actions as appropriate to the facility:

(1) Directly notify~~ing~~ direct consignees about the animal food being recalled, including how to return or dispose of the affected animal food;

(2) Notify~~ing~~ the public about any hazard presented by the animal food when appropriate to protect animal and human health;

(3) Conduct~~ing~~ effectiveness checks (as described in part 7 of this chapter) to verify the recall has been carried out; and

(4) ~~The proper disposition~~Appropriately dispose of recalled animal food (e.g., ~~destroying,~~

reprocessing, ~~or~~reworking, diverting to another use that would not present a safety concern, or destroying) ~~of the recalled animal food~~.

§ 507.39 Preventive control management components.

(a) Except as provided by paragraphs (b) and (c) of this section, the preventive controls required under § 507.36 are subject to the following preventive control management components as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control:

(1) Monitoring in accordance with § 507.40;

(2) Corrective actions and corrections in accordance with § 507.42; and

(3) Verification in accordance with § 507.45.

(b) The supplier program established in § 507.37 is subject to the following preventive control management components as appropriate to ensure the effectiveness of the supplier program, taking into account the nature of the hazard controlled before receipt of the raw material or ingredient:

(1) Corrective actions and corrections in accordance with § 507.42, taking into account the nature of any supplier non-conformance;

(2) Review of records in accordance with § 507.49(a)(4)(ii); and

(3) Reanalysis in accordance with § 507.50.

(c) The recall plan established in § 507.38 is not subject to the requirements of paragraph (a) of this section.

§ 507.~~40~~39 Monitoring.

(a) ~~The owner, operator, or agent in charge of a facility~~As appropriate to the preventive control you must:

(1) Eestablish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive controls; and. ~~These procedures must include:~~

~~(1) What preventive controls will be monitored;~~

~~(2) Who will perform the monitoring;~~

~~(3) How the monitoring will be performed;~~

~~(4) What parameter will be measured, if applicable;~~

~~(5) Frequency with which the monitoring will be performed; and~~

~~(6) Any additional information needed to ensure appropriate monitoring of the preventive controls.~~

(2) Monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed.

(b) ~~The owner, operator, or agent in charge of a facility~~You must monitor the preventive controls with ~~sufficient~~adequate frequency to provide assurance that the preventive controls are consistently performed.

(c) All ~~M~~monitoring of preventive controls in accordance with this section must be documented in records that are subject to verification in accordance with § 507.45(~~b)(1~~a)(2) and records review in accordance with § 507.~~45(c)(1~~49(a)(4)(i~~) and (c)(2~~).

§ 507.42 Corrective actions~~.~~ and corrections.

(a) ~~The owner, operator, or agent in charge of a facility~~As appropriate to the preventive control, except as provided by paragraph (c) of this section:

(1)(i) You must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented.

(ii) The corrective action procedures required by paragraph (a)(1)(i) of this section must include procedures to address, as appropriate:

(A) The presence of a pathogen or appropriate indicator organism in animal food detected as a result of product testing conducted in accordance with § 507.49(a)(2); and

(B) The presence of an environmental pathogen or appropriate indicator organism detected through the environmental monitoring conducted in accordance with § 507.49(a)(3).

(2) The corrective action procedures must describe the steps to be taken to ensure that:

(~~1~~i) Appropriate action is taken to identify and correct a problem that has occurred with implementation of a preventive control;

(ii) Appropriate action is taken when necessary, to reduce the likelihood that the problem will recur;

(~~2~~iii) All affected animal food is evaluated for safety; and

(~~3~~iv) All affected animal food is prevented from entering into commerce if ~~the owner, operator, or agent in charge of the facility~~you cannot ensure the affected animal food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

(b)(1) Except as provided by paragraph (c) of this section, you are subject to the requirements of paragraph (b)(2) of this section if any of the following circumstances apply:

(i) ~~If a~~A preventive control is not properly implemented and a specific corrective action procedure has not been established,

(ii) ~~ or a~~A preventive control is found to be ineffective; or~~,~~

(iii) A review of records in accordance with § 507.49(a)(4) finds that the records are not complete, the activities conducted did not occur in accordance with the food safety plan, or appropriate decisions were not made about corrective actions.

(2) If any of the circumstances listed in paragraph (b)(1) of this section apply, ~~the owner, operator, or agent in charge of a facility~~ you must:

(~~1~~i) Take corrective action to identify and correct the problem ~~to~~;

(ii) ~~r~~Reduce the likelihood that the problem will recur;

(~~2~~iii) Evaluate all affected animal food for safety;

(~~3~~iv) As necessary, prevent affected animal food from entering commerce as would be done following the corrective action procedure under paragraph (a)(2) of this section; and

(~~4~~v) When appropriate, ~~R~~reanalyze the food safety plan in accordance with § 507.~~45(c)~~50 to determine whether modification of the food safety plan is required.

(c) You do not need to comply with the requirements of paragraphs (a) and (b) of this section for conditions and practices that are not consistent with the sanitation controls in § 507.36(c)(2)(i) or (ii) if you take action, in a timely manner, to correct such conditions and practices.

~~(c)~~(d) ~~When~~ All corrective actions (and, when appropriate, corrections) ~~are~~ taken in accordance with this section~~, they~~ must be documented in ~~written~~ records. These records are subject to verification in accordance with § 507.45~~(b)(2)~~(a)(3) and records review in accordance with § 507.49(a)(4)(i)~~45(c)(1) and (c)(2)~~.

§ 507.45 Verification.

(a) Verification activities must include, as appropriate to the preventive control:

(1) Validation in accordance with § 507.47;

(2) Verification that monitoring is being conducted as required by §507.39 (and in accordance with § 507.40);

(3) Verification that appropriate decisions about corrective actions are being made as

required by §507.39 (and in accordance with § 507.42);

(4) Verification of implementation and effectiveness in accordance with § 507.49; and

(5) Reanalysis in accordance with § 507.50.

~~(f)~~(b) All verification activities ~~taken~~conducted in accordance with this section must be documented in records.

§ 507.47 Validation.

(a) Except as provided by paragraph (~~a~~b)(3) of this section, ~~the owner, operator, or agent in charge of a facility~~you must validate that the preventive controls identified and implemented in accordance with § 507.36 to control the significant hazards ~~identified in the hazard analysis as reasonably likely to occur~~ are adequate to do so as appropriate to the nature of the preventive control.

(b) The validation of the preventive controls:

(1) Must be performed (or overseen) by a qualified individual:

(i) Prior to implementation of the food safety plan or, when necessary, during the first 6 weeks of production; and

(ii) Whenever a reanalysis of the food safety plan reveals the need to do so;

(2) Must include collecting and evaluating scientific and technical information (or, when such information is not available or is ~~insufficient~~inadequate, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control ~~the~~significant hazards ~~that are reasonably likely to occur~~; and

(3) Need not address:

(i) The sanitation controls in § 507.36(~~d~~c)(2); ~~and~~

(ii) The supplier program in § 507.37; and

~~(ii)~~(iii) The recall plan in § 507.38.

~~(b) The owner, operator, or agent in charge of a facility must verify that:~~

~~(1) Monitoring is conducted as required by § 507.39;~~

~~(2) Appropriate decisions about corrective actions are being made as required by § 507.42;~~

~~(3) The preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur; and~~

~~(4) The activities conducted must include, as appropriate to the facility and the animal food, calibration of process monitoring and verification instruments.~~

§ 507.49 Verification of implementation and effectiveness.

(a)~~(c) The owner, operator, or agent in charge of a facility~~You must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the significant hazards.~~ that are reasonably likely to occur by ensuring that a qualified individual is conducting (or overseeing):~~ To do so, you must conduct activities that include the following, as appropriate to the facility, the animal food, and the nature of the preventive control:

(1) Calibration of process monitoring and verification instruments;

(2) Product testing for a pathogen (or appropriate indicator organism) or other hazard;

(3) Environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of an animal food with an environmental pathogen is a significant hazard, by collecting and testing environmental samples; and

~~(1)~~(4) ~~A r~~Review of the following records ~~in~~within the ~~timeframe~~ specified timeframes, by (or under the oversight of) a qualified individual, to ensure the records are complete, the

activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions:

(i) Monitoring and corrective action records within a week after the records are ~~made~~created; and

(ii) Records of calibration ~~of instruments~~, product testing, environmental monitoring, and supplier verification activities within a reasonable time after the records are created.

~~(2) A review of the records in paragraphs (c)(1)(i) and (c)(1)(ii) of this section to ensure:~~

~~(i) The records are complete;~~

~~(ii) The activities reflected in the records occurred in accordance with the food safety plan;~~

~~(iii) The preventive controls are effective;~~

~~(iv) Appropriate decisions were made about corrective actions.~~

(b)~~(d)The owner, operator, or agent in charge of a facility must establish and implement written procedures, a~~ As appropriate to the facility, ~~and~~ the ~~animal~~ food, and the nature of the preventive control, you must establish and implement written procedures for the following activities:

(1) The method and frequency of calibrating process monitoring instruments and verification instruments as required by paragraph (a)(1) of this section.

(2) Product testing as required by paragraph (a)(2) of this section. Procedures for product testing must:

(i) Be scientifically valid;

(ii) Identify the test microorganism(s) or other analyte(s);

(iii) Specify the procedures for identifying samples, including their relationship to

specific lots of product;

(iv) Include the procedures for sampling, including the number of samples and the sampling frequency;

(v) Identify the test(s) conducted, including the analytical method(s) used;

(vi) Identify the laboratory conducting the testing; and

(vii) Include the corrective action procedures required by § 507.42(a)(1).

(3) Environmental monitoring as required by paragraph (a)(3) of this section. Procedures for environmental monitoring must:

(i) Be scientifically valid;

(ii) Identify the test microorganism(s);

(iii) Identify the locations from which samples will be collected and the number of sites to be tested during routine environmental monitoring. The number and location of sampling sites must be adequate to determine whether preventive controls are effective;

(iv) Identify the timing and frequency for collecting and testing samples. The timing and frequency for collecting and testing samples must be adequate to determine whether preventive controls are effective;

(v) Identify the test(s) conducted, including the analytical method(s) used;

(vi) Identify the laboratory conducting the testing; and

(vii) Include the corrective action procedures required by § 507.42(a)(1~~) Conduct~~)(ii).

§ 507.50 Reanalysis.

(a)~~(e) The owner, operator, or agent in charge of a facility~~ You must~~:~~ conduct a reanalysis of the food safety plan:

(~~i~~1) At least once every 3 years;

(~~ii~~2) Whenever a significant change is made in the activities conducted at ~~the~~your facility ~~operated by such owner, operator, or agent in charge~~ if the change creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard;

(~~iii~~3) Whenever ~~the owner, operator, or agent in charge~~ you become~~s~~ aware of new information about potential hazards associated with the animal food;

(4) Whenever appropriate after an unanticipated animal food safety problem in accordance with § 507.42(b); and

~~(iv) Whenever a preventive control is not properly implemented and a specific corrective action procedure has not been established;~~

(~~v~~5) Whenever you find that a preventive control is ~~found to be~~ ineffective~~; and~~.

~~(vi) Whenever FDA requires a reanalysis in response to newly identified hazards and developments in scientific understanding.~~

(~~2~~b) You must ~~C~~complete the reanalysis required by paragraph (a) of this section and implement any additional preventive controls needed to address the hazard identified, if any, before the change in activities at the facility is operative or, when necessary, during the first 6 weeks of production.

(~~3~~c) You must ~~R~~revise the written food safety plan if a significant change is made~~,~~ or document the basis for the conclusion that no ~~additional or revised preventive controls~~revisions are needed~~; and~~.

(~~4~~d) ~~Ensure the reanalysis is performed (or overseen) by a~~ A qualified individual must perform (or oversee) the reanalysis.

(e) You must conduct a reanalysis of the food safety plan when FDA determines it is necessary to respond to new hazards and developments in scientific understanding.

§ 507.~~48~~51 Modified requirements that apply to a facility solely engaged in the storage of packaged animal food that is not exposed to the environment.

(a) The owner, operator, or agent in charge of a facility solely engaged in the storage of packaged animal food that is not exposed to the environment must conduct the following activities for any such refrigerated packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin formation by, microorganisms of animal or human health significance:

(1) Establish and implement temperature controls adequate to significantly minimize or prevent the growth of, or toxin formation by, microorganisms of animal or human health significance;

(2) Monitor the temperature controls with sufficient frequency to provide assurance they are consistently performed;

(3) Take appropriate corrective actions if there is a problem with the temperature controls for such refrigerated packaged animal food to:

(i) Correct the problem and reduce the likelihood that the problem will recur;

(ii) Evaluate all affected animal food for safety; and

(iii) Prevent the animal food from entering commerce, if the owner, operator, or agent in charge of the facility cannot ensure the affected animal food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act;

(4) Verify that temperature controls are consistently implemented by:

(i) Calibrating temperature monitoring and recording devices;

(ii) Reviewing records of calibration within a reasonable time after the records are made; and

(iii) Reviewing records of monitoring and corrective actions taken to correct a problem with the control of temperature within a week after the records are made;

(5) Establish and maintain the following records:

(i) Records documenting the monitoring of temperature controls for any such refrigerated packaged animal food;

(ii) Records of corrective actions taken when there is a problem with the control of temperature for any such refrigerated packaged animal food; and

(iii) Records documenting the verification activities.

(b) The records that a facility must establish and maintain under paragraph (a)(5) of this section are subject to the requirements of subpart F of this part.

§ 507.~~50~~53 Requirements applicable to a qualified individual and a qualified auditor.

(a) One or more qualified individuals must do or oversee the following:

(1) Preparation~~e~~ of the food safety plan (§ 507.~~30~~31(b));

(2) Validation~~e~~ of the preventive controls (§ 507.~~45(a)~~47(b)(1));

(3) ~~Conduct a r~~Review of records ~~for implementation and effectiveness of preventive controls and appropriateness of corrective actions~~ (§ 507.~~45(c)~~(a)(4));

(4) ~~Perform a r~~Reanalysis of the food safety plan (§ 507.~~45(e)~~50(d)).

(b) A qualified auditor must conduct an onsite audit (§ 507.37(d)).

~~(b)~~(c)(1) To be a qualified~~, an~~ individual, the individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided

an individual with knowledge at least equivalent to that provided through the standardized curriculum. This individual may be, but is not required to be, an employee of the facility.

(2) To be a qualified auditor, a qualified individual must have technical expertise obtained by a combination of training and experience appropriate to perform the auditing function.

~~(c)~~(d) All applicable training must be documented in records, including the date of the training, the type of training, and the person(s) trained.

§ 507.55 Implementation ~~R~~records ~~required for this subpart C~~.

(a) ~~The owner, operator, or agent in charge of a facility~~You must establish and maintain the following records documenting implementation of the food safety plan:

~~(1) The written food safety plan, including the written hazard analysis, preventive controls, monitoring procedures, corrective action procedures, verification procedures, and recall plan;~~:

(~~2~~1) Records that document the monitoring of preventive controls;

(~~3~~2) Records that document corrective actions;

(~~4~~3) Records that document verification, including, as applicable, those related to:

(i) Validation;

(ii) Verification of ~~M~~monitoring;

(iii) Verification of ~~C~~corrective actions;

(iv) Calibration of process monitoring and verification instruments;

(v) Product testing;

(vi) Environmental monitoring;

(vii) Records review; and

(vii) Reanalysis; ~~and~~

(4) Records that document the supplier program; and

(5) Records that document applicable training for the qualified individual and the qualified auditor.

(b) The records that ~~the owner, operator, or agent in charge of a facility~~you must establish and maintain are subject to the requirements of subpart F of this part.

Subpart D--Withdrawal of an Exemption Applicable to a Qualified Facility

§ 507.60 Circumstances that may lead FDA to withdraw an exemption applicable to a qualified facility.

(a) FDA may withdraw the exemption applicable to a qualified facility under § 507.5(d):

(~~a~~1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility; or

(~~b~~2) If FDA determines that it is necessary to protect the public (human or animal ~~or human~~) health and prevent or mitigate a foodborne illness outbreak based on ~~conduct or~~ conditions or conduct associated with the qualified facility that are material to the safety of the animal food manufactured, processed, packed, or held at such facility.

(b) Before FDA issues an order to withdraw an exemption applicable to a qualified facility, FDA:

(1) May consider one or more other actions to protect the public (human or animal) health or mitigate a foodborne illness outbreak, including, a warning letter, recall, administrative detention, suspension of registration, import alert, seizure, and injunction;

(2) Must notify the owner, operator, or agent in charge of the facility, in writing of circumstances that may lead FDA to withdraw the exemption, and provide an opportunity for the

owner, operator, or agent in charge of the facility to respond in writing, within 10 calendar days of the date of receipt of the notification, to FDA's notification; and

(3) Must consider the actions taken by the facility to address the circumstances that may lead FDA to withdraw the exemption.

§ 507.62 Issuance of an order to withdraw an exemption applicable to a qualified facility.

~~(a) If FDA determines that an exemption applicable to a qualified facility under § 507.5(d) should be withdrawn, any officer or qualified employee of FDA may issue an order to withdraw the exemption.~~

(~~b~~a) An FDA District Director in whose district the qualified facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine), or an FDA official senior to such Director, must approve an order to withdraw the exemption before the order is issued.

(b) Any officer or qualified employee of FDA may issue an order to withdraw the exemption after it has been approved in accordance with paragraph (a) of this section.

(c) FDA must issue an order to withdraw the exemption to the owner, operator, or agent in charge of the facility.

(d) FDA must issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order.

§ 507.65 Contents of an order to withdraw an exemption applicable to a qualified facility.

An order to withdraw an exemption applicable to a qualified facility under § 507.5(d) must include the following information:

(a) The date of the order;

(b) The name, address, and location of the qualified facility;

(c) A brief, general statement of the reasons for the order, including information relevant to:

(1) An active investigation of a foodborne illness outbreak that is directly linked to the facility; or

(2) Conduct or conditions associated with a qualified facility that are material to the safety of the animal food manufactured, processed, packed, or held at such facility.

(d) A statement that the facility must either:

(1) ~~c~~Comply with subpart C of this part on the date that is ~~60~~120 calendar days after the date of receipt of the order; or

(2) Appeal the order within 10 calendar days of the date of receipt of the order in accordance with the requirements of § 507.69.

(e) The text of section 418(l) of the Federal Food, Drug, and Cosmetic Act and of this subpart D;

(f) A statement that any informal hearing on an appeal of the order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in § 507.73;

(g) The mailing address, telephone number, email address, and facsimile number of the FDA district office and the name of the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the same information for the Director of the Division of Compliance in the Center for Veterinary Medicine); and

(h) The name and the title of the FDA representative who approved the order.

§ 507.67 Compliance with, or appeal of, an order to withdraw an exemption applicable to a qualified facility.

(a) ~~The owner, operator, or agent in charge of a qualified facility that~~ If you receive~~s~~ an

order under § 507.~~60~~65 to withdraw an exemption applicable to that facility under § 507.5(d), you must either:

(1) Comply with applicable requirements of this part within ~~60~~120 calendar days of the date of receipt of the order; or

(2) Appeal the order within 10 calendar days of the date of receipt of the order in accordance with the requirements of § 507.69.

(b) Submission of an appeal, including submission of a request for an informal hearing, will not operate to delay or stay any administrative action, including enforcement action by FDA, unless the Commissioner, as a matter of discretion, determines that delay or a stay is in the public interest.

(c) If ~~the owner, operator, or agent in charge of the qualified facility~~ you appeal~~s~~ the order, and FDA confirms the order, ~~the owner, operator, or agent in charge of the facility~~ you must comply with applicable requirements of this part within ~~60~~120 calendar days of the date of receipt of confirmation of the order.

§ 507.69 Procedure for submitting an appeal.

(a) To appeal an order to withdraw an exemption applicable to a qualified facility under § 507.5(d), ~~the owner, operator, or agent in charge of the facility~~you must:

(1) Submit the appeal in writing to the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine), at the mailing address, email address, or facsimile number identified in the order within 10 calendar days of the date of receipt of the order;

(2) Respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which the owner, operator, or agent in charge of the facility relies.

(b) In a written appeal of the order withdrawing an exemption provided under § 507.5(d), the owner, operator, or agent in charge of the facility may include a written request for an informal hearing as provided in § 507.71.

§ 507.71 Procedure for requesting an informal hearing.

(a) If ~~the owner, operator, or agent in charge of the facility appeals~~you appeal the order, ~~the owner, operator, or agent in charge of the facility~~you:

(1) May request an informal hearing; and

(2) Must submit any request for an informal hearing together with ~~its~~your written appeal submitted in accordance with § 507.69 within 10 calendar days of the date of receipt of the order.

(b) A request for an informal hearing may be denied, in whole or in part, if the presiding officer determines that no genuine and substantial issue of material fact has been raised by the material submitted. If the presiding officer determines that a hearing is not justified, written notice of the determination will be given to the owner, operator, or agent in charge of the facility explaining the reason for the denial.

§ 507.73 Requirements applicable to an informal hearing.

If the owner, operator, or agent in charge of the facility requests an informal hearing, and FDA grants the request:

(a) The hearing will be held within 10 calendar days after the date the appeal is filed or, if applicable, within a timeframe agreed upon in writing by the owner, operator, or agent in charge of the facility and FDA.

(b) The presiding officer may require that a hearing conducted under this subpart be completed within 1 calendar day, as appropriate.

(c) FDA must conduct the hearing in accordance with part 16 of this chapter, except that:

(1) The order withdrawing an exemption under §§ 507.62 and 507.65, rather than the notice under § 16.22(a) of this chapter, provides notice of opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter.

(2) A request for a hearing under this subpart must be addressed to the FDA District Director (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine) as provided in the order withdrawing an exemption.

(3) Section 507.75, rather than § 16.42(a) of this chapter, describes the FDA employees who preside at hearings under this subpart.

(4) Section 16.60(e) and (f) of this chapter does not apply to a hearing under this subpart. The presiding officer must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. The presiding officer must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 2 calendar days of issuance of the report. The presiding officer will then issue the final decision.

(5) Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. The presiding officer's report of the hearing and any comments on the report by the hearing participant under § 507.73(c)(4) are part of the administrative record.

(6) No party shall have the right, under § 16.119 of this chapter to petition the Commissioner for reconsideration or a stay of the presiding officer's final decision.

(7) If FDA grants a request for an informal hearing on an appeal of an order withdrawing an exemption, the hearing must be conducted as a regulatory hearing under part 16 of this chapter, except that § 16.95(b) does not apply to a hearing under this subpart. With respect to a regulatory hearing under this subpart, the administrative record of the hearing specified in §§ 16.80(a)(1), (a)(2), (a)(3), and (a)(5), and 507.73(c)(5) constitutes the exclusive record for the presiding officer's final decision. For purposes of judicial review under § 10.45 of this chapter, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

§ 507.75 Presiding officer for an appeal and for an informal hearing.

The presiding officer for an appeal, and for an informal hearing, must be an FDA Regional Food and Drug Director or another FDA official senior to an FDA District Director.

§ 507.77 Timeframe for issuing a decision on an appeal.

(a) If the owner, operator, or agent in charge of a facility appeals the order without requesting a hearing, the presiding officer must issue a written report that includes a final decision confirming or revoking the withdrawal by the 10th calendar day after the appeal is filed.

(b) If the owner, operator, or agent in charge of a facility appeals the order and requests an informal hearing:

(1) If FDA grants the request for a hearing and the hearing is held, the presiding officer must provide a 2 calendar day opportunity for the hearing participants to review and submit comments on the report of the hearing under § 507.73(c)(4), and must issue a final decision within 10 calendar days after the hearing is held; or

(2) If FDA denies the request for a hearing, the presiding officer must issue a final decision on the appeal confirming or revoking the withdrawal within 10 calendar days after the date the appeal is filed.

§ 507.80 Revocation of an order to withdraw an exemption applicable to a qualified facility.

An order to withdraw an exemption applicable to a qualified facility under § 507.5(d) is revoked if:

(a) The owner, operator, or agent in charge of the facility appeals the order and requests an informal hearing, FDA grants the request for an informal hearing, and the presiding officer does not confirm the order within the 10 calendar days after the hearing, or issues a decision revoking the order within that time; or

(b) The owner, operator, or agent in charge of the facility appeals the order and requests an informal hearing, FDA denies the request for an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time; or

(c) The owner, operator, or agent in charge of the facility appeals the order without requesting an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time.

§ 507.83 Final agency action.

Confirmation of a withdrawal order by the presiding officer is considered a final agency action for purposes of 5 U.S.C. 702.

§ 507.85 Reinstatement of an exemption that was withdrawn.

(a) If the FDA District Director in whose district your facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary

Medicine) determines that a facility has adequately resolved problems with the conditions and conduct that are material to the safety of the animal food manufactured, processed, packed, or held at the facility and that continued withdrawal of the exemption is not necessary to protect public (human and animal) health and prevent or mitigate a foodborne illness outbreak, the FDA District Director in whose district your facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine) will, on his own initiative or on the request of a facility, reinstate the exemption.

(b) You may ask FDA to reinstate an exemption that has been withdrawn under the procedures of this subpart as follows:

(1) Submit a request, in writing, to the FDA District Director in whose district your facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine); and

(2) Present data and information to demonstrate that you have adequately resolved the problems with the conditions or conduct that are material to the safety of the animal food manufactured/ processed, packed, or held at your facility, such that continued withdrawal of the exemption is not necessary to protect public (human and animal) health and prevent or mitigate a foodborne illness outbreak.

(c) If your exemption was withdrawn under § 507.60(a)(1) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your facility, FDA will reinstate your exemption under § 507.5(d), and FDA will notify you in writing that your exempt status has been reinstated.

(d) If your exemption was withdrawn under both § 507.60(a)(1) and (2) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the

outbreak is not directly linked to your facility, FDA will inform you of this finding and you may ask FDA to reinstate your exemption under § 507.5(d) in accordance with the requirements of paragraph (b) of this section.

Subpart E--[Reserved]

Subpart F--Requirements Applying to Records That Must Be Established and Maintained

§ 507.~~100~~200 Records subject to the requirements of this subpart F.

(a) Except as provided by paragraphs (d) and (e) of this section, all records required by this part are subject to all requirements of subpart F.

(b) Records required by this part are subject to the disclosure requirements under part 20 of this chapter.

(c) All records required by this part must be made promptly available to a duly authorized representative of the Secretary of Health and Human Services upon oral or written request.

(d) The requirements of § 507.106 apply only to the written food safety plan.

(e) The requirements of § 507.102(a)(2), (a)(4), and (a)(5) and (b) do not apply to the records required by § 507.7(e) pertaining to qualified facilities.

§ 507.~~102~~ 202 General requirements applying to records.

(a) Records must:

(1) Be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records, which must be kept in accordance with part 11 of this chapter;

(2) Contain the actual values and observations obtained during monitoring and as appropriate, during verification activities;

(3) Be accurate, indelible, and legible;

(4) Be created concurrently with performance of the activity documented; and

(5) Be as detailed as necessary to provide history of work performed.

(b) All records must include:

(1) The name and location of the plant or facility;

(2) The date and time of the activity documented;

(3) The signature or initials of the person performing the activity; and

(4) Where appropriate, the identity of the product and the production code, if any.

§ 507.~~106~~ 206 Additional requirements applying to the food safety plan.

The food safety plan must be signed and dated by the owner, operator, or agent in charge of the facility upon initial completion and upon any modification.

§ 507.~~108~~208 Requirements for record retention.

(a) All records required by this part must be retained at the plant or facility for at least 2 years after the date they were prepared.

(b) Records that relate to the general adequacy of the equipment or processes being used by a facility, including the results of scientific studies and evaluations, must be retained at the facility for at least 2 years after their use is discontinued (e.g., because the facility has updated the written food safety plan (§ 507.30) or records that document validation of the written food safety plan (§ 507.45(a)).

(c) Except for the food safety plan, offsite storage of records is permitted after 6 months following the date that the record was made if such records can be retrieved and provided onsite within 24 hours of request for official review. The food safety plan must remain onsite. Electronic records are considered to be onsite if they are accessible from an onsite location.

(d) If the plant or facility is closed for a prolonged period, the records may be transferred

to some other reasonably accessible location, but must be returned to the plant or facility within 24 hours for official review upon request.

§ 507.212 Use of existing records.

(a) Existing records (e.g., records that are kept to comply with other Federal, State, or local regulations, or for any other reason) do not need to be duplicated if they contain all of the required information and satisfy the requirements of this subpart F. Existing records may be supplemented as necessary to include all of the required information and satisfy the requirements of this subpart F.

(b) The information required by this part does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by this part may be kept either separately or combined with the existing records.

PART 579--IRRADIATION IN THE PRODUCTION, PROCESSING, AND HANDLING OF ANIMAL FEED AND PET FOOD

10. The authority citation for 21 CFR part 579 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 348, 371.

11. In § 579.12, add the following sentence to the end of the paragraph to read as follows:

§ 579.12 Incorporation of regulations in part 179.

* * * Any facility that treats animal feed and pet food with ionizing radiation must comply with the requirements of part 507 of this chapter and other applicable regulations.